

REMARKS

After entry of this amendment, claims 1, 2, 4-9 and 25-38 are pending. Claims 3 and 14-24 have been cancelled without prejudice or disclaimer. New claims 27-38 have been added and find support *inter alia* in the original claims. Further support for the new claims is found throughout the specification, for example, at page 1, lines 3-10 and 16-19, and page 9, lines 17-19. New claim 27 finds further support in the specification, for example, at page 40, lines 22-26, and page 55, lines 1-6. New claims 29 and 37 find further support, for example, at page 9, lines 14-17. New claim 36 finds further support, for example, at page 67, lines 29-30, and Figure 7. The claims have been amended without prejudice or disclaimer and find support *inter alia* in the original claims. Claim 1 finds further support in the specification, for example, at page 9, lines 17-19, page 40, lines 22-26, and page 55, lines 1-6. Claim 4 finds further support, for example, at page 9, lines 14-17. No new matter has been added.

Applicants respectfully request entry of the above amendments because the finality of the present Action is inappropriate for the reasons discussed below in the section entitled "Finality of the Present Action." Alternatively, Applicants also believe that the above amendments should be entered under 37 CFR §1.116 practice because the above amendments put the claims in condition for allowance or, alternatively, in better form for consideration on appeal by further narrowing the scope of the claims. The above amendments also do not present any new issues that require further consideration or search. Additionally, the total number of claims is not increased in view of the cancellation of claims 3 and 14-24. Accordingly, entry under 37 CFR §1.116 is correct.

In the specification at page 62, the paragraphs located at lines 32-35 have been deleted as being repetitive of the paragraphs located at lines 1-6 at page 63. No new matter has been added.

Finality of the Present Action

Applicants respectfully request that the finality of the present action be withdrawn because the finality of the present Office Action is inappropriate for at least the following reasons.

First, the Examiner provides several new grounds of rejections in the present Action, among which is a new ground of rejection under 35 U.S.C. § 112, first paragraph, alleging that

the claims lack adequate written support, a new ground of rejection under 35 U.S.C. § 102(b) based on a newly cited reference, Spychalla *et al.* (hereinafter “Spychalla”), and a new ground of rejection under 35 U.S.C. § 103(a) based on the combination of Knutzon (previously cited), Spychalla, and another newly cited reference, Browse *et al.* (hereinafter “Browse”). Pursuant to MPEP § 706.07(a), a second or any subsequent action on the merits in any application will not be made final if it includes a rejection, on newly cited art. Because the references Spychalla and Browse are newly cited references and the written description and obviousness rejections are new rejections in the present Action, the action should not have been made final.

Second, the Examiner alleges that the new rejections were necessitated by Amendments. Applicants strongly disagree. The amendments to former claim 1 further narrows the scope of the claimed genus of ω -3-desaturases. Without acquiescing to the rejection, if the genus as amended lacked adequate written support, the genus prior to the amendment would also have lacked adequate written support. Accordingly, the new ground of rejection under 35 U.S.C. § 112, first paragraph, was not necessitated by the amendments. Furthermore, Applicants submit that the subject matter on which the new grounds of rejection under 35 U.S.C. § 102(b) and 103(a) are based was already in the claims before the amendments. Accordingly, at least the newly cited Spychalla reference could have been brought forth prior to the amendments and the new grounds of rejection could have been made prior to the previous amendments and as such was not necessitated by the amendments. Therefore, the finality of the Office Action was improper for this additional reason.

Because the rejections are new and based on newly cited references and because at least one of the newly cited references should have been brought forth and the new grounds of rejection could have been made prior to the previous amendments, the new grounds of the rejection are not necessitated by the amendments. For at least these reasons, Applicants respectfully request that the finality of the Office Action dated November 18, 2009 be reconsidered and withdrawn.

Claim Objections

The Examiner objects to claim 1 as being unclear and requires further clarification. Applicants respectfully disagree. However, to expedite prosecution, claim 1 has been amended without prejudice or disclaimer to recite the compounds produced by the claimed method with

more specificity. In light of the above amendment, it is believed that the present objection is overcome. Accordingly, Applicants respectfully requests reconsideration and withdrawn of the objection.

Claim 26 is objected to for reciting "fatty acid" in singular form. In response, claim 26 has been amended without prejudice or disclaimer by adopting the Examiner's suggestion. Applicants believe that the present amendment overcomes the objection. Reconsideration and withdrawn of the objection is respectfully requested.

New Claim Rejections under 35 U.S.C. § 112

Claims 1-9, 25 and 26 are newly rejected for alleged lack of written description support. Applicants respectfully disagree and traverse the rejection. However, to expedite prosecution, the claims have been amended without prejudice or disclaimer to recite the ω -3-desaturases with more specificity. Applicants respectfully submit that the claims as amended overcome the rejection for the following reasons.

As set forth in *Vas-Cath Inc. v. Mahurkar*, 19 USPQ 2d 1111, 1116 (Fed. Cir. 1991), the test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to one skilled in the art that the inventor had possession of the claimed subject matter at the time of filing. Possession may be shown in a variety of ways including description of an actual reduction to practice. *See* MPEP § 2163 (citations omitted).

It is noted initially that, as acknowledged by the Examiner, the specification describes the sequence of SEQ ID NO: 1 that encodes SEQ ID NO: 2 by its actual structure (i.e. sequences). Because the genetic code and its redundancies were known in the art at the time of filing, the disclosure of SEQ ID NO: 2, combined with the pre-existing knowledge in the art, would have put one in possession of the genus of nucleic acids that encodes SEQ ID NO: 2. With the aid of a computer, one skilled in the art could have identified all of the nucleic acids that encode a polypeptide having at least 95% identity with SEQ ID NO: 2. Thus, one of ordinary skill in the art would conclude that Applicants were in possession of the claimed genus at the time the application was filed. *See*, "Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, 'Written Description' Requirement," at page 37-38.

Furthermore, as described in the specification at page 59, line 32, to page 60, line 5, natural allelic variations (e.g. genetic polymorphisms) can lead to alterations in the amino acid sequences of an enzyme within a population, bringing about a variation of 1-5% in the nucleotide sequence of the gene without altering the functional activity of the enzyme. Accordingly, the claim scope created by the recitation of at least 95% identity with SEQ ID NO: 1 includes the expected range of natural polymorphic variants, which should certainly be within the scope of the invention.

Moreover, the specification further provides an actual reduction to practice of the claimed processes by describing the use of an ω -3-desaturase from *Phytophthora infestans*, an ω -3-desaturase that is capable of desaturating C22:4 ω -6-fatty acid to C22:5 ω -3-fatty acid (see Figure 7), for producing compounds comprising one or more C18-, C20-, and/or C22-polyunsaturated fatty acids in a transgenic organism or to increase the content of C18-, C20- and/or C22-polyunsaturated fatty acids in oils, lipids, or fatty acids in an organism. Thus, one skilled in the art, upon reading the present specification, would reasonably conclude that the inventors had possession of the claimed subject matter at the time of filing.

For at least the above reasons and in light of the present amendments, it is respectfully submitted that the specification provides adequate written description for the claims as amended. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Double Patenting

Claims 1-9, 25 and 26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as unpatentable over claim 3 of co-pending U.S. Application Serial No. 10/566,944. Applicants respectfully disagree. However, to expedite prosecution, and because this is a provisional rejection, Applicants will consider filing an appropriate terminal disclaimer if the rejection stands when the claims are otherwise found allowable.

New Claim Rejections under 35 U.S.C. § 102

Claims 1, 3-9 and 25 are newly rejected under 35 U.S.C. § 102(b) as being anticipated by Spychalla.

The Examiner asserts that Spychalla teaches an ω -3-desaturase that desaturates C20 and C18 fatty acids as well as transgenic Arabidopsis plants expressing such a desaturase. The

Examiner further asserts that the oil extracted from Spychalla's transgenic plants has the PUFA in a concentration of at least 5% by weight of the total lipid content. Applicants respectfully disagree. However, to expedite prosecution, the claims have been amended without prejudice or disclaimer to recite the ω -3-desaturases with more specificity. Applicants respectfully submit that the claims as amended overcome the rejection for the following reasons.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegall Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987). "[U]nless a reference discloses within the four corners of the document not only all the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102." *Net MoneyIN Inc. v. VeriSign Inc.*, 545 F.3d 1359 (Fed. Cir. 2008).

As amended, the claims require that the ω -3-desaturase used in the claimed process is either (1) capable of desaturating C22:4 ω -6-fatty acid to C22:5 ω -3-fatty acid, or (2) encoded by a nucleic acid sequence comprising (a) the nucleic acid sequence of SEQ ID NO: 1, (b) a nucleic acid sequence encoding the amino acid sequence of SEQ ID NO: 2, (c) a nucleic acid sequence having at least 95% identity with the nucleic acid sequence of SEQ ID NO: 1, or (d) a nucleic acid sequence encoding an amino acid sequence having at least 95% identity with the amino acid sequence of SEQ ID NO: 2.

Spychalla discloses identification of an animal ω -3 fatty acid desaturase by heterologous expression in *Arabidopsis*. The ω -3-desaturase disclosed in Spychalla is arguably capable of desaturating only C18 or C20 ω -6 substrates, but not C22 ω -6 substrates. See Spychalla, last sentence in Abstract at page 1142. Further, the ω -3-desaturase disclosed in Spychalla (GenBank accession No. L41807, see Spychalla at page 1143, right Col., last sentence of the last full paragraph) shares only about 12% sequence identity at the nucleotide level and about 24% sequence identity at the amino acid level with SEQ ID NO: 1 and 2 of the present application, respectively, when aligned with ClustalW program using the default parameters. Accordingly, Spychalla does not anticipate the present claims as amended because it does not disclose, expressly or inherently, each and every element as set forth in the claims as amended.

For at least the above reasons and in light of the present amendments, reconsideration and withdrawal of the rejection is respectfully requested.

New Claim Rejections under 35 U.S.C. § 103

Claims 1-9, 25 and 26 are newly rejected under 35 U.S.C. § 103(a) as being obvious over Knutzon, in view of Spychalla and Browse.

The Examiner asserts that Knutzon teaches a method of making PUFAs in a plant by transforming a Brassica plant with an ω -3-desaturase coding sequence, and further combining with other fatty acid biosynthesis genes. The Examiner acknowledges that Knutzon does not teach an ω -3-desaturase that desaturates C20 or C22 fatty acids, but relied on Spychalla and Browse for such teaching. The Examiner alleges that, because of the recognition of the value of producing long chain PUFAs in transgenic plants as taught by Knutzon, it would have been obvious to a skilled in the art to substitute the enzyme used in Knutzon with other known desaturase coding sequences such as that taught by Spychalla in view of Browse. Applicants respectfully disagree and traverse the rejection.

However, to expedite prosecution, the claims have been amended without prejudice or disclaimer to recite the ω -3-desaturases with more specificity. As amended, the claims requires that the ω -3-desaturase to be either (1) capable of desaturating C22:4 ω -6-fatty acid to C22:5 ω -3-fatty acid, or (2) encoded by a nucleic acid sequence comprising (a) the nucleic acid sequence of SEQ ID NO: 1, (b) a nucleic acid sequence encoding the amino acid sequence of SEQ ID NO: 2, (c) a nucleic acid sequence having at least 95% identity with the nucleic acid sequence of SEQ ID NO: 1, or (d) a nucleic acid sequence encoding an amino acid sequence having at least 95% identity with the amino acid sequence of SEQ ID NO: 2. Applicants respectfully submit that the claims as amended overcome the rejection for the following reasons.

The examiner bears the initial burden of establishing *prima facie* obviousness. See *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). To support a *prima facie* conclusion of obviousness, the prior art must disclose or suggest all the limitations of the claimed invention. See *In re Lowry*, 32 F.3d 1579, 1582, 32 USPQ2d 1031, 1034 (Fed. Cir. 1994).

Knutzon discloses a method of making polyunsaturated fatty acids in a plant by co-transforming a Brassica plant with the coding sequence of a Δ -5-desaturase, a Δ -6-desaturase, a

Δ -12-desaturase, and a Δ -15-desaturase from *Mortierella alpina*. As the Examiner pointed out, the ω -3-desaturase taught in Knutzon also named as Δ -15-desaturase. As discussed in the Response dated August 27, 2009, this particular ω -3-desaturase (or Δ -15-desaturase) converts linoleic acid (LA, 18:2) to linolenic acid (ALA, 18:3). See Col. 4, lines 49-52, and Figure 1. Accordingly, the ω -3-desaturase (or Δ -15-desaturase) taught in Knutzon has substrate specificity only to C18-fatty acids, but not C20- or C22-fatty acids, as acknowledged by the Examiner in the instant Office Action at page 7, paragraph 18. It is thus clear that Knutzon does not teach or suggest an ω -3-desaturase or the use thereof as recited in the claims as amended.

The combination of Knutzon with Spychalla and Browse does not remedy this deficiency. As discussed above, Spychalla discloses identification of an animal ω -3 fatty acid desaturase by heterologous expression in Arabidopsis. As stated in the Abstract at page 1142, Spychalla characterizes the disclosed ω -3 fatty acid desaturase as being one that recognizes a range of 18- and 20-carbon ω -6 substrates. See Spychalla, last sentence in Abstract at page 1142. Thus, the ω -3 desaturase taught in Spychalla is not capable of desaturating 22-carbon ω -6 substrates. Further, as mentioned above, the ω -3-desaturase disclosed in Spychalla shares only about 12% sequence identity at the nucleotide level and about 24% sequence identity at the amino acid level with SEQ ID NO: 1 and 2 of the present application, respectively. Thus, Spychalla also does not teach or suggest an ω -3-desaturase as recited in the claims as amended.

Browse discloses the fat-1 gene of *C. elegans* and recombinantly expresses such a gene in Arabidopsis and yeast to demonstrate that this fat-1 gene has ω -3 desaturase activity. See Browse, Abstract. Although Browse arguably demonstrates that the disclosed ω -3 desaturase may convert C22:5 ω -6-fatty acid to C22:6 ω -3-fatty acid (see Example 4 of Browse), there is no evidence in the Browse reference that the disclosed ω -3 desaturase is capable of desaturating C22:4 ω -6-fatty acid to C22:5 ω -3-fatty acid. Moreover, a sequence comparison reveals that the ω -3-desaturase disclosed in Browse shares only about 12% sequence identity at the nucleotide level and about 24% sequence identity at the amino acid level with SEQ ID NO: 1 and 2 of the present application, respectively, when aligned with ClustalW program using the default parameters. Thus, similar to Spychalla, Browse also does not teach or suggest an ω -3-desaturase as recited in the claims as amended.

Because none of the cited Knutzon, Spsychalla, and Browse references teaches or suggests an ω -3-desaturase as recited in the claims as now amended, it is clear that the combination of Knutzon, Spsychalla, and Browse does not teach or suggest at least this particular limitation of the claimed processes. Because the combined teaching of the cited references does not teach or suggest all the limitations of the claimed invention, a *prima facie* case of obviousness has not been established. For at least the above reasons, Applicants respectfully request reconsideration and withdrawal of the rejection.

CONCLUSION

In view of the above remarks and further in view of the above amendments, Applicants respectfully request withdrawal of the rejections and allowance of the claims. If any outstanding issues remain, the Examiner is invited to telephone the undersigned at the number given below.

Applicants reserve all rights to pursue the non-elected claims and subject matter in one or more divisional applications, if necessary.

This response is filed within the three-month period for response from the mailing of the Office Communication. No fee is believed due. However, if a fee is due, please charge our Deposit Account No. 03-2775, under Order No. 13987-00019-US from which the undersigned is authorized to draw.

Respectfully submitted,

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